CEIV
Center of Excellence
for Independent Validators

Pharmaceutical Handling

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Specialized in Temperature Controlled Shipments for Pharmaceuticals

Pharma Process Forum

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CEIV
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The International Air Cargo Certification Program

for

Operators of Temperature Sensitive Air Shipments

of

Pharmaceutical Products

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Pharmaceutical Handling

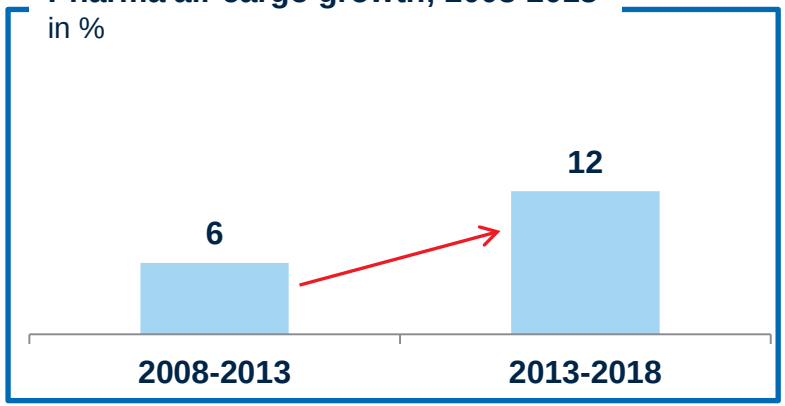
What? · Why? · How? · Where?

A concerted effort of the Air Cargo Industry to improve the level of competency, operational and technical preparedness for Temperature Sensitive Air Freight Shipments of Pharmaceutical Products.

The impact of mode shift on pharmaceutical logistics

The pharmaceutical industry has relied heavily on the airline industry for its speed and efficiency but air cargo's share of global pharmaceutical products transport has dropped

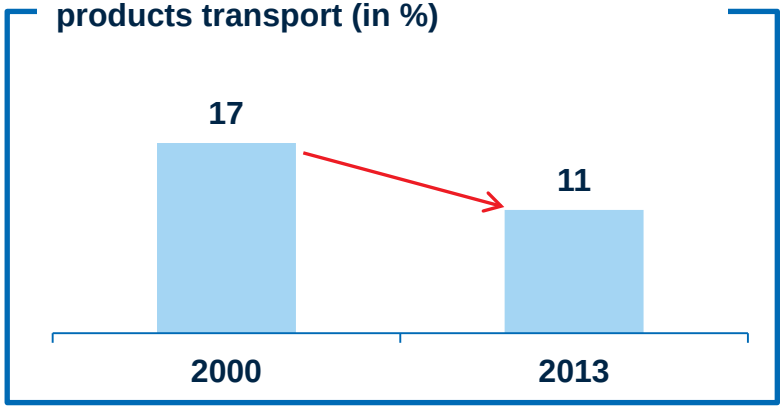
Pharma air cargo growth; 2008-2018
in %



Over the past 10 years, air carriers, handlers and freight forwarders have responded with branded products and services to grab a share of this lucrative and niche market.

HOWEVER

Air cargo's share of global pharmaceutical products transport (in %)

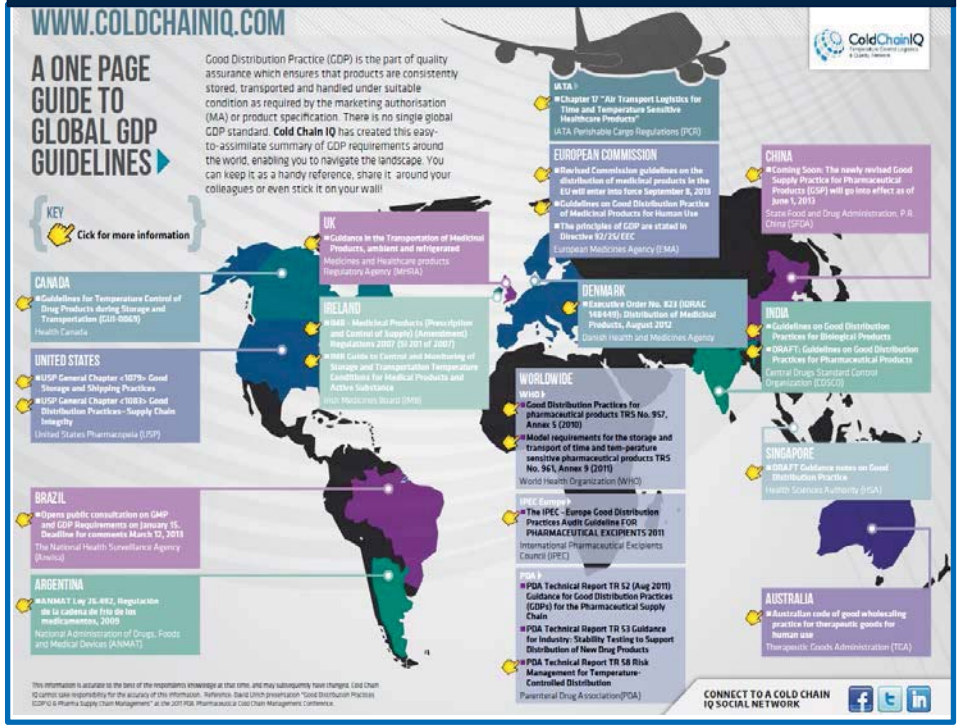


Source: Pharmaceutical Commerce

Air Cargo Industry Concerns and Challenges

Heavily regulated industry with no global standards and certification for handling of pharmaceutical products

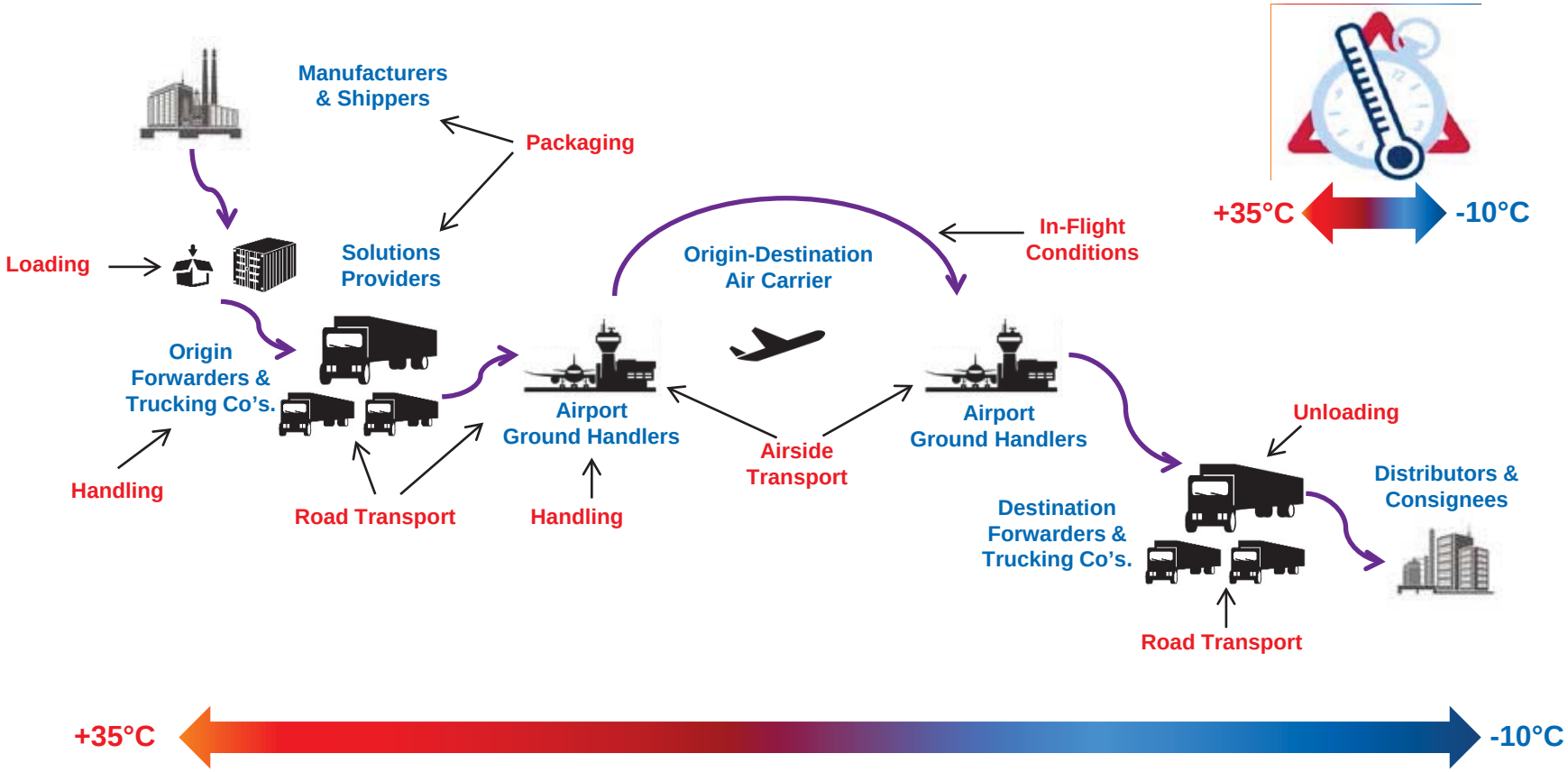
Regulations for transporting pharmaceutical products vary around the world



- **Increasing number of regulations** around the world to implement and comply with.
- **Increasing number of audits.**
- **Airlines, GHAs and forwarders subjected to multiple audits** for handling, transportation and distribution (*e.g. WHO Appendix 5, EU 92/25/EEC, IATA PCR Chapter 17 & TCR).*
- **No global certification** for handling of pharmaceutical products.

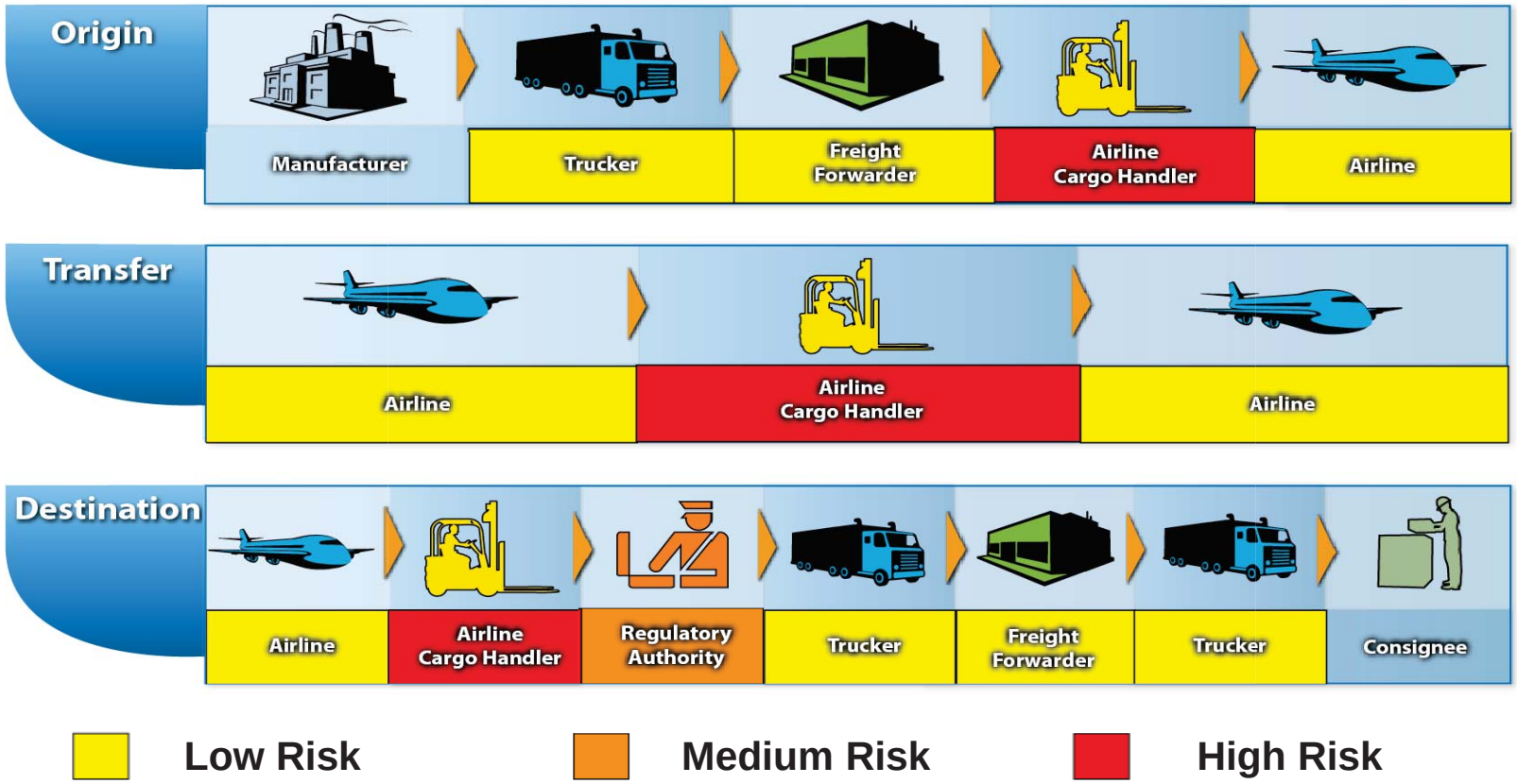
Air Cargo Supply Chain Challenges

From origin to destination pharmaceutical products can be exposed to different climates



Air Cargo Industry Concerns and Challenges

Temperature Excursions – Where do they occur?



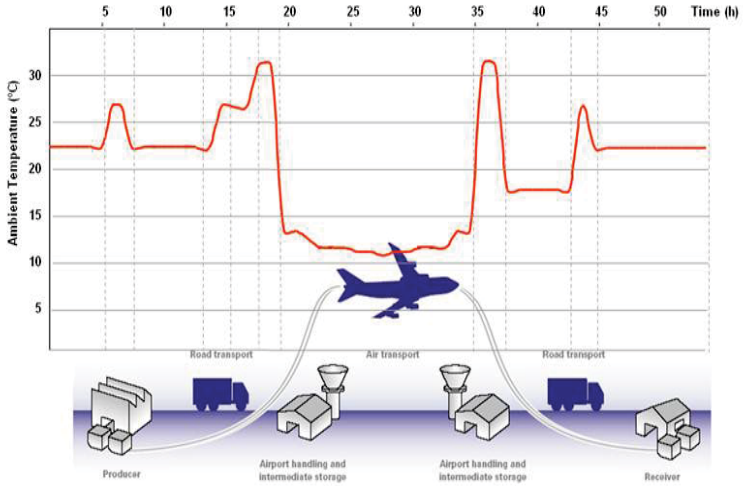
Source: Expeditors

Critical Issues Raised by the Shippers

Increasing shift in pharmaceuticals transported by sea due to air cargo challenges

- **More than 50% of all temperature excursions occur while the package is in the hands of airlines/airports**
  - Temperature deviation denature the product, render it worthless and be harmful to the health of the patient
  - Products can be lost, scrapped, returned leading to significant costs

- **Annual product losses between US$2.5-12.5 billion due to various reasons including temperature excursions during transport and shipping.**



Due to a lack of compliance, standardization, accountability and transparency across the air transport supply chain

The use of air-mode transportation is re-considered unless industry partners ensure quality services

Shippers Expectations in Cold Chain

Shippers need service providers that maintain product integrity and efficacy during transportation

- **Compliance**, **standardization**, **accountability and transparency** across the supply chain
- **Properly trained stakeholders** on regulations and standards
- **Adequately equipped facilities** throughout the supply chain
- **Global certification** for handling of pharmaceutical cargo
- **Common audit format** to minimize the disruptions and increase effectiveness
- Ability to **easily search and identify stakeholders that meet requirements**

CEIV Pharma

To ensure the integrity of the product throughout the supply chain

OBJECTIVES

Prevent sanitary issues caused by temperature excursions during transportation.

Improve handling of in compliance with existing regulations &standards.

Ensure product integrity

Elevate level staff competency through efficient and robust training program.

Create a global and consistent certification that industry can rely on.

CEIV Pharma targets

Who does CEIV Pharma target? The supply chain

Trucking Companies

Freight Forwarders

Distributors

Ground Handlers

Airlines

Airports

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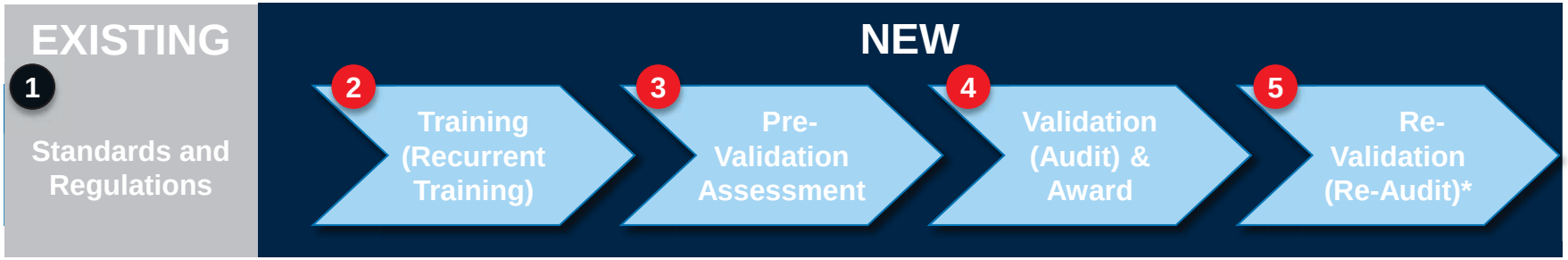
Approach of the CEIV

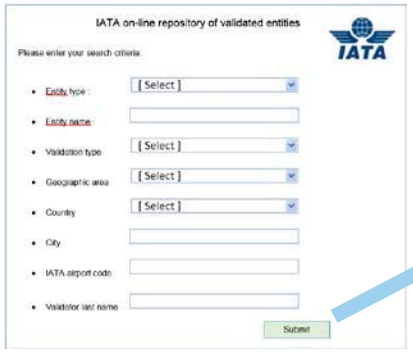


- **Advocate** for globally accepted standards and regulations
- **Train instructors** on behalf of the airlines, cargo and ground handlers
- **Manage** the pool of qualified instructors
- **Train** the **Independent Validators** to a common standard and validation methodology
- **Train operational staff**
- Run on-site **pre-audits** to prepare for validation
- **Conduct the validations**
- **Manage the database of Independent validators**
- **Manage the database of certified companies**

Visibility for CEIV Pharma validated entities

Validated entities will become visible on IATA's website

Search



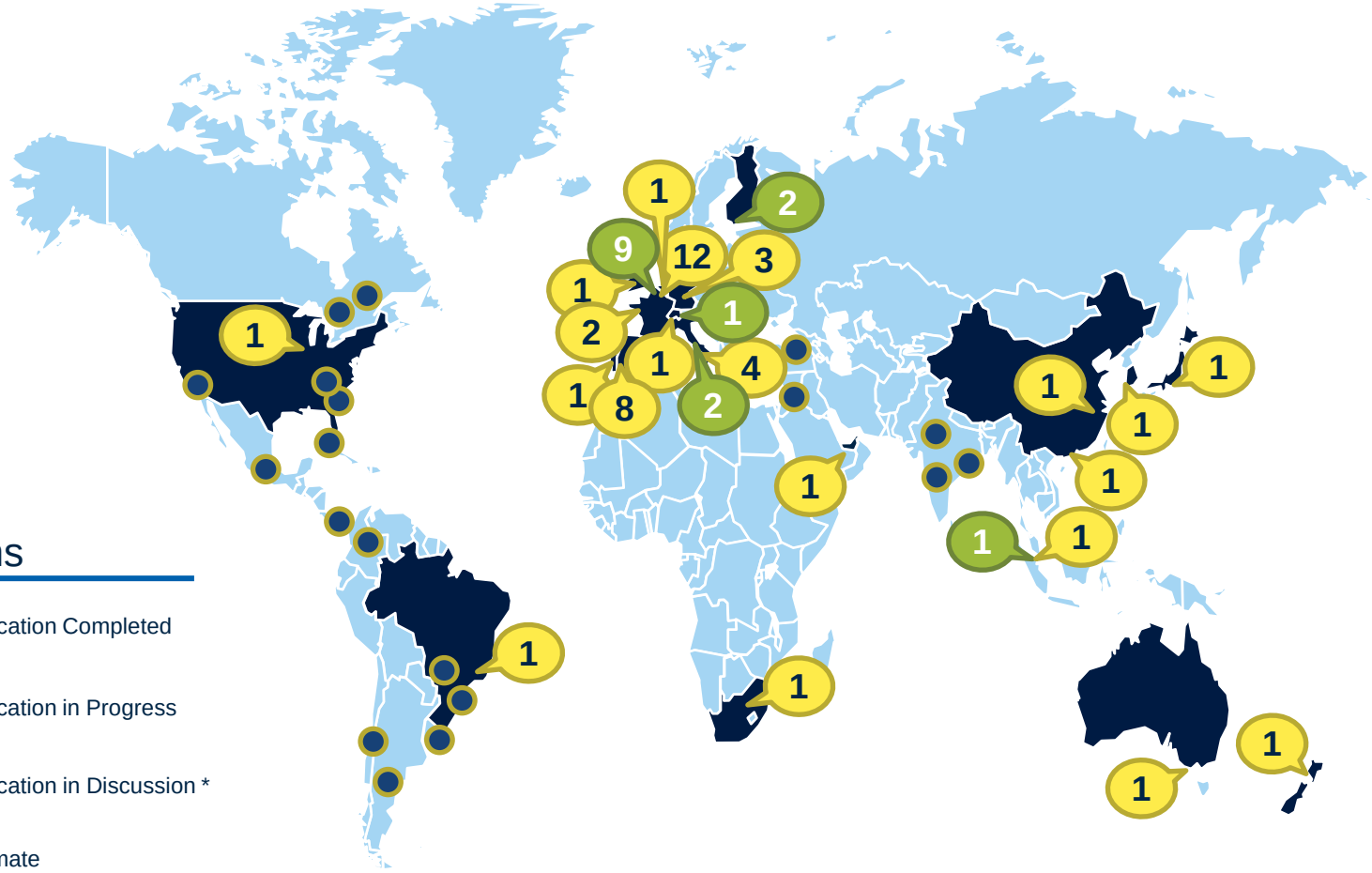
Results

Type	Name	City	Country	IATA Airport Code	End of validity date of audit: EU 185/2010-RA3*	EU 185/2010-KC3*	IATA CEIV Pharma
	Dog screener PLC	MusterCity2	Thailand	SDF	03-Sep-18		
	Easy forwarding	MusterCity3	India	ABC	04-Jan-19		03-Nov-18
	AirlineX	MusterCity5	The Netherland	AMS			05-Aug-18
	AirlineX	MusterCity2	Thailand	BKK			05-Sep-19
	GHA_ABC	MusterCity	Columbia	ABC	15-Jul-19		
	GHA_ABC	MusterCity	Columbia	RTY	04-Jun-19		
	GHA_ABC	MusterCity	Columbia	CBA	04-Jun-19		05-May-18
	Shipping unlimited	MusterCity4	Vietnam	SDG		08-Apr-19	24-Jun-17

Details on a validation

CEIV Pharma

Certified Pharmaceutical Trade Lanes Development



Locations

15 Certification Completed

44 Certification in Progress

97 Certification in Discussion *

* Estimate

THANK YOU

For further information, contact:

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